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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,498	01/20/2004	Francis Michon	3842-4043US2	4609

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,498	MICHON ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 6/24/04.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,3-22,25-27,33-40,47,51-53,55 and 58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1,3-22,25-27,33-40,47,51-53,55 and 58 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Restriction / Species Election

1) Claim 2 has been canceled.

Claims 1, 3-22, 25-27, 33-40, 47, 51-53, 55 and 58 have been amended.

New claims 59-65 have been added.

Claim 1 and 3-65 are under prosecution.

2) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-28, 37-40 and 59-61, drawn to an N-propionated polysaccharide-protein conjugate and a vaccine comprising the same, classified in class 424, subclass 831

II. Claims 29-36, drawn to a method of making beta-propionamido-linked polysaccharide- or oligosaccharide-protein conjugate, classified in class 536, subclass 127

III. Claims 41-47, drawn to a method of immunizing a mammal comprising administering to the mammal the vaccine of claim 37, classified in class 424, subclasses 234.1

IV. Claims 48-54, drawn to an immunoglobulin or antigen binding fragment thereof to the beta-propionamido-linked oligosaccharide or polysaccharide conjugate, classified in class 530, subclass 387.5

V. Claims 55-58 and 62-65, drawn to a method of passive immunization against a disease-causing organism or disease-causing cell comprising administering an immunoglobulin of claim 48 or 51, classified in class 424, subclass 150.1

3) Inventions I-V are distinct from one another. Inventions I and IV are drawn to two distinct products: (a) polysaccharide- or oligosaccharide-protein conjugate; and (b) an immunoglobulin or antigen binding fragment. A polysaccharide is a carbohydrate composed of saccharide repeat units whereas antibodies are glycoproteins which include IgG that comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. The two products are distinct molecules divergent with regard to their composition, structure, and function, each requiring a separate and non-coextensive search. Searching inventions I and IV together would impose a search burden.

4) Inventions II, III and V are drawn to distinct methods, which differ from one another in the product or reagent(s) used therein, methods steps and parameters, method objectives, and ultimate goals used. The products used in these methods are divergent with regard to their structure and/or function, and classes/subclasses, each requiring separate and non-coextensive searches. The method of making a conjugate is unrelated to the method of immunizing a mammal, and the method of passive immunization. Therefore, searching the above-identified inventions together would not be coextensive and impose a serious search burden.

5) Inventions IV and V are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the immunoglobulin of invention IV can be used in a materially different process, for example, as a source of immunogen to raise anti-idiotypic antibodies.

6) Inventions I and III, and inventions I and V, are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the conjugate of invention I can be used in a materially different process, for example, as a source of coating antigen in an *in vitro* diagnostic assay to measure levels of polysaccharide-specific antibodies.

7) Inventions I and II are related as product and process of making the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the product of invention I can be made by a process materially different from the process of invention II, for example, by recombinant fusion or transgenic technology.

Searching inventions I and III, inventions I and V, and inventions I and II, together would impose a serious search burden. These inventions have a separate status in the art as shown by their different classifications. The search for inventions III, V and II would require a text search for the

claimed methods in addition to a search for each product used therein. Moreover, even if each product were known, the methods, which use the products, may be novel and unobvious in view of the preamble or active steps.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, and since a search performed for one would not be co-extensive for the other, restriction for examination purposes as indicated is proper.

8) (A) If invention I, is elected, Applicants must further elect one of the following polysaccharide or oligosaccharide species from: (a) Group B *Streptococcus* (claims 5 and 4); (b) *Meningococcus* (claims 4, 6 and 39); (c) *E. coli* K1 (claims 4, 7 and 39); (d) *E. coli* K92 (claims 4, 7 and 39); (e) *Pneumococcus* type 4 (claims 4, 7 and 39); (f) *Pneumococcus* 14 (claims 4, 7 and 39); (g) *Streptococcus* group A (claims 4, 7 and 39); (h) *Streptococcus* group B (claims 5, 4 and 39); (i) *Streptococcus* group C (claims 4, 7 and 39); (j) *Salmonella* (claims 4 and 39); (k) *Klebsiella* (claims 4 and 39); (l) *Pseudomonas* (claims 4 and 39); (m) yeast (claims 3, 17 and 38); and (n) cancer cell (claims 3, 17 and 38). Claims 3, 17 and 38 are generic to the bacterial polysaccharide or oligosaccharides identified above. Claims 1, 8-16, 18-28, 37, 40 and 59-61 are generic.

(B) If invention II is elected, Applicants must further elect one of the following polysaccharide or oligosaccharide species from: (a) yeast (claim 33); (b) cancer cells (claim 33); (c) *E. coli* (claim 34); (d) *Meningococcus* (claim 34); (e) *Pneumococcus* (claim 34); (f) *Streptococcus* (claim 34); (g) *Neisseria* (claim 34); (h) *Salmonella* (claim 34); (i) *Klebsiella* (claim 34); and (j) *Pseudomonas* (claim 34). Claim 33 is generic to the bacterial polysaccharide or oligosaccharides identified above. Claims 29-32, 35 and 36 are generic.

(C) If invention III is elected, Applicants must further elect one of the following disease species from: (a) *Streptococcus pneumoniae* (claim 42); (b) Group B *Streptococcus* (claim 43); (c) Group B *Neisseria meningitidis* (claim 44); (d) Group C *Neisseria meningitidis* (claim 45); (e) *Haemophilus influenzae* type B (claim 46); and (f) a cell-caused disease (claim 41). Claim 41 is generic to the disease-causing organisms identified above.

(D) If invention IV or V is elected, Applicants must further elect one of the following anti-polysaccharide antibody species: (a) *E. coli* (claim 53); (b) *Meningococcus* (claim 53); (c) *Pneumococcus* (claim 53); (d) *Streptococcus* (claim 53); (e) *Neisseria* (claim 53); (f)

Salmonella (claim 53); (g) *Klebsiella* (claim 53); (h) *Pseudomonas* (claim 53); yeast (claim 52); and cancer cells (claims 52 and 55). Claim 52 is generic to bacterial polysaccharide antibodies identified above. Claims 48-51 and 54-58 are generic.

(E) If invention I, is elected, Applicants must further elect one of the following second immunogenic component species in claims 25 and 40: (a) DTP; (b) DTPa; (c) Td; (d) DTaP-Hib; and (e) DTaP-IPV-Hib.

(F) The instant application contains claims directed to patentably distinct species of the claimed invention. Election to one of the following protein species, which are distinct in their structure or amino acid sequences, is required: (a) tetanus toxoid (claims 8, 35 and 61); (b) diphtheria toxoid (claims 8, 35 and 61); (c) *Neisseria meningitidis* outer membrane protein (claims 8, 10, 35 and 61); (d) C-beta protein from group B *Streptococcus* (claims 8, 35 and 61); (e) non-IgA-binding C-beta protein from group B *Streptococcus* (claims 8 and 35); (f) cholera toxin subunit B (claim 61); (g) pneumolysoid (claims 8 and 61); (h) *Pseudomonas aeruginosa* toxoid (claim 61); and (i) pertussis toxoid (claim 61). Claim 9 is generic.

Each of the species identified above requires a separate and individual structure search.

13) Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14) The Office has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be rejoined. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

15) In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for

patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.* Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. 37 CFR 1.143.

17) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

18) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

19) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to

Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Acting Supervisor, Albert Navarro, can be reached on (571) 272-0861.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2006

S. DEVI, PH.D.
PRIMARY EXAMINER